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EXAMINER	
DOUGHERTY, SEAN PATRICK	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,074	GLOCKER ET AL.	
	Examiner	Art Unit	
	Sean P. Dougherty	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) *6-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04 October 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This is the initial Office action based on the 10/552074 application filed October, 2005. Claims 1-13, as originally filed, are currently pending and have been considered below. Claims 1 & 13 are independent.

Specification

2. The abstract of the disclosure is objected to because the abstract contains more than 150 words. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: **a)** patent in the specification says "6459972" and should be --6450972--; **b)** page 2 line 24 refers to claim 1 & claim 3, claims may not be mentioned in the specification. Appropriate correction is required.

Claim Objections

4. Claims 2-9 are objected to because of the following informalities: **a)** claims 6-9 line 2 say "liquid substance" and should be --electrically conductive liquid substance--; **b)** claim 9 lines 2-3 say "have an amplitude of about max. 4 mm and a frequency of about max 15 Hz" and should say --have a maximum amplitude of about 4 mm and a maximum frequency of about 15 Hz--; c) claims 2-9 line 1 each state "Method" and should be --The method. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, for the following reasons:

a. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner notes that "a low voltage/high frequency current" is indefinite being that it is not known whether the limitation should be interpreted as "a low voltage OR high frequency current" or as "a low voltage AND high frequency current".

b. Regardings claim 9-12, the phrase "respectively" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

c. Regarding claims 3, 5, 7, 8 & 9, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

d. Regarding claim 10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

e. Claim 1 recites the limitations "the mammal" (line 4), "the catheter lumen" (line 6), "the external surface" (line 9), "the subject" and "the leakage current" (lines 9-10), "the leakage current parameters" (line 13), "the measurement

location" (lines 15-16). There is insufficient antecedent basis for this limitation in these claims.

f. Claim 12 recites the limitation "the pressure values" (line 3). There is insufficient antecedent basis for this limitation in these claims.

g. Claim 13 recites the limitation "the detected leakage current" and "the converter" (line 9). There is insufficient antecedent basis for this limitation in these claims.

h. Claims 10-12 recite the limitation "Use of the method of claim 1" which is an inappropriate use claim and should be changed to "The method of claim 1".

6. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

i. In the present instance, claims 1 & 11 (line 1) recite the broad recitation "for performing pressure", and the claim also recites "respectively pressure profile" which is the narrower statement of the range/limitation.

j. In the present instance, claims 7-12 recite the broad recitation of ranges and the claims also recite narrower statement of the range/limitation.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter regarding the recitation "an electrode placed at the external surface of the subject". Such is not patent eligible subject matter because the subject is being claimed as part of the apparatus.

Claim Rejections - 35 USC § 103

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-7 & 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoll (US 6450972 B1) in view of Nicholas et al. (US 5433708 A).

Regarding claims 1 & 6, Knoll discloses a method comprising:

a) introducing into the mammal a catheter having at least a portion of its wall which is sufficiently flexible to be deflected by external pressure ("pressure profile measurements, e.g. in urology, proctology, cardiology ... carried out with the aid of catheters" Abstract lines 5-7; "tubular flexible hollow body" Abstract line 8 and col. 1, lines 30-38);

b) introducing progressively into the catheter lumen an electrically conductive liquid substance (col. 2 lines 13-14) while applying simultaneously to it alternative current ("alternating current" col. 2 line 1; "measurement of the electrical resistance, measurement of the electrical capacity, measurement of acoustic resonance" Abstract lines 14-16, Col. 4, lines 31-40);

c) detecting by means of an electrode (#21) placed at the external surface of the subject the leakage current induced by the liquid substance traveling through the catheter ("electrical capacity is measured between the electrically conductive substance [I] and an electrically conductive medium [18] which surrounds the tube [1"]; "medium [18] can be a common salt solution, to which contact is provided with the aid of a metal electrode [21]" col. 5 lines 12-29);

d) transferring the leakage current thus recorded to a converter suitable to convert the leakage current parameters provided thereto into corresponding pressure values ("the pressure profile is here measured on the basis of a capacity measurement with the aid of a capacity measuring instrument #7" col. 5 lines 13-15); and

e) displaying the pressure values as such, or as a function of the measurement location or measurement period or both to afford corresponding pressure profiles (Figs. 1a-c and Col. 7, lines 3-16). Examiner notes that it is known to one of ordinary skill in that art that displaying results of a measurement is commonly known technique, the purpose of taking measurements is to display results in a multitude of forms for the use in medical diagnosis, surgery etc.

Knoll discloses an electrically conductive liquid substance (col. 2 lines 13-14). Knoll does not appear to explicitly disclose a method comprising applying mechanical oscillations to the electrically conductive liquid substance introduced progressively into the catheter lumen, progressing step-by-step. However, Nicholas et al. teaches a method comprising applying mechanical oscillations to an electrically conductive liquid substance introduced progressively into a catheter lumen, progressing step-by-step

(#72; "inducing an oscillating flow of a ... fluid" col. 1 lines 16-17; "power supply and controller may be connected to a mechanical actuator [72] which drives a syringe assembly [74] to create a reciprocating pump mechanism" col. 11 lines 38-41).

Knoll and Nicholas et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly catheters placed in a living mammal to perform a medical operation. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and Nicholas et al. before him or her to modify the electrically conductive liquid substance introduced progressively into the catheter lumen of Knoll to be influenced by applying mechanical oscillations to the electrically conductive liquid substance, progressing the liquid step-by-step in the lumen of Nicholas et al.; this is applying a known technique of applying mechanical oscillation means to a known device ready for improvement, being an apparatus for performing pressure measurements, to yield the predictable result of the electroconductive liquid oscillating in movement when entering the lumen of the catheter. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a "method for inducing an oscillating flow of ... fluid" (col. 1 lines 16-17) as taught by Nicholas et al. Therefore, it would have been obvious to combine Knoll with Nicholas et al. to obtain the invention in the instant claim 1.

Regarding claim 2, Knoll discloses a method wherein the alternative current is a low voltage/high frequency current ("alternating current" col. 2 line 1; "measurement of the electrical resistance, measurement of the electrical capacity, measurement of

acoustic resonance" Abstract lines 14-16; "electrical voltages of U>10 mV" col. 2 line 2). Knoll does not appear to explicitly disclose a method wherein the mechanical oscillations have controlled amplitude and frequency. However, Nicholas et al. discloses a method wherein the mechanical oscillations have controlled amplitude and frequency (col. 11 lines 51-54).

Knoll and Nicholas et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly catheters placed in a living mammal to perform a medical operation. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and Nicholas et al. before him or her to modify the alternative low voltage/high frequency current of Knoll to be influenced by applying mechanical oscillations wherein the mechanical oscillations have controlled amplitude and frequency of Nicholas et al.; this is applying a known technique of applying controlled mechanical oscillation means to a known device ready for improvement, being an apparatus for performing pressure measurements, to yield the predictable result of the electroconductive liquid oscillating in controlled movement when entering the lumen of the catheter. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a "method for inducing an oscillating flow of … fluid" (col. 1 lines 16-17) as taught by Nicholas et al. Therefore, it would have been obvious to combine Knoll with Nicholas et al. to obtain the invention in the instant claim 2.

Regarding claim 3, Knoll discloses a method wherein the catheter is made of innocuous polymer plastic material (col. 2 line 5-7), preferably of non-conductive innocuous polymer plastic material. Examiner notes the phrase "preferably" renders the claim indefinite because it is unclear whether limitation following the phrase is part of the claimed invention.

Regarding claim 4, Knoll discloses wherein the catheter is a single lumen (Fig. 8) or a multi-lumen catheter (Fig. 9).

Regarding claim 5, Knoll discloses a method wherein the electrically conductive liquid substance is an aqueous liquid (col. 2 lines 13-14), preferably a saline solution ("NaCl" col. 2 line 14). Examiner notes the phrase "preferably" renders the claim indefinite because it is unclear whether limitation following the phrase is part of the claimed invention.

Regarding claim 7, Knoll discloses a method wherein the alternative current voltage applied to the liquid substance is comprised between about 500mV and about 6V ("electrical voltages of U>10 mV" col. 2 line 2), preferably between about 1 and about 4V. Examiner notes the phrase "preferably" renders the claim indefinite because it is unclear whether limitation following the phrase is part of the claimed invention.

Regarding claim 9, Knoll does not appear to explicitly disclose a method wherein the mechanical oscillations applied to the liquid substance have an amplitude of about max. 4 mm ("aspirating and expelling relatively small volumes of ... medium through the catheter, typically in the range from about 0.1 ml to 3 ml" col. 3 lines 63-68; "catheters having diameters in the range from about 1.5 mm to 3 mm" col. 10 lines 32-34) and a

frequency of about max 15 Hz ("oscillation will typically be performed at from about 0.1 Hz to 5 Hz" col. 3 line 67-68), preferably of about 2mm, respectively about 10 Hz. Examiner notes the phrase "preferably" renders the claim indefinite because it is unclear whether limitation following the phrase is part of the claimed invention. Examiner notes the phrase "respectively" renders the claim indefinite because it is unclear whether limitation following the phrase is part of the claimed invention.

Knoll and Nicholas et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly catheters placed in a living mammal to perform a medical operation. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and Nicholas et al. before him or her to modify the fluid flow of Knoll to have the amplitude of about max. 4 mm and a frequency of about max 15 Hz of Nicholas et al.; this is simply applying a known technique of applying mechanical oscillation means connected downwards to a peristaltic pump to a known device ready for improvement being an apparatus for performing pressure measurements, to yield the predictable result of the electroconductive liquid oscillating in movement when entering the lumen of the catheter. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a "method for inducing an oscillating flow of ... fluid" (col. 1 lines 16-17) as taught by Nicholas et al. Therefore, it would have been obvious to combine Knoll with Nicholas et al. to obtain the invention in the instant claim 9.

Regarding claim 10, Knoll discloses a method performing pressure, respectively pressure profile measurements in mammal body tracts or cavities such as lung, esophagus, stomach, intestine, urinary tract or bladder, or blood vessels ("pressure profile measurements, e.g. in urology, proctology, cardiology ... carried out with the aid of catheters" Abstract lines 5-7; "tubular flexible hollow body" Abstract line 8). Examiner notes that it known to one of ordinary skill in the art that urology and cardiology catheters correspond to pressure profiles measurements in the urinary tract/bladder and blood vessels, respectively. Examiner notes the phrase "such" renders the claim indefinite because it is unclear whether limitation following the phrase is part of the claimed invention.

Regarding claim 11, Knoll discloses a method for performing real time pressure, respectively pressure profile measurements ("sensor system for measuring pressure profiles" Abstract lines 1-2).

Regarding claim 12, Knoll discloses a method for performing ex-temporaneum pressure, respectively pressure profiles measurements by recording the pressure values provided by the converter and by displaying them at a time different from that of the leakage current recording (Figs. 1a-c). Examiner notes that it is known to one of ordinary skill in that art that displaying results of a measurement is commonly known technique, the purpose of taking measurements is to display results in a multitude of forms for the use in medical diagnosis, surgery etc.

Regarding claim 13, Knoll discloses a source of an electrically conductive liquid substance (col. 2 lines 13-14) connected to an alternative current source ("alternating

current" col. 2 line 1; "measurement of the electrical resistance, measurement of the electrical capacity, measurement of acoustic resonance" Abstract lines 14-16); pumping (col. 4 line 35) means fitted directly to the source of liquid substance; an electrode (#21) placed at the external surface of the subject for recording and then transferring the detected leakage current to the converter ("electrical capacity is measured between the electrically conductive substance [I] and an electrically conductive medium [18] which surrounds the tube [1"]; "medium [18] can be a common salt solution, to which contact is provided with the aid of a metal electrode [21]" col. 5 lines 12-29); a converter ("the pressure profile is here measured on the basis of a capacity measurement with the aid of a capacity measuring instrument #7" col. 5 lines 13-15) suitable for deriving pressure values from the leakage current parameters which have been transferred thereto; and means suitable to display pressure values as such, or as a function of the measurement location or measurement period or both ("measurement system in which a pressure profile can be measured" col. 1 lines 26-27). Examiner notes that it is known to one of ordinary skill in that art that displaying results of a measurement is commonly known technique, the purpose of taking measurements is to display results in a multitude of forms for the use in medical diagnosis, surgery etc. Knoll does not appear to explicitly disclose peristaltic pumping means and mechanical oscillation means connected downwards to peristaltic pumping means. However, Nicholas et al. teaches peristaltic pumping means and mechanical oscillation means connected downwards to peristaltic pumping means (#72; "inducing an oscillating flow of a ... fluid" col. 1 lines 16-17; "power supply and controller may be connected to a mechanical actuator 72 which

drives a syringe assembly 74 to create a reciprocating pump mechanism" col. 11 lines 38-41).

Knoll and Nicholas et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly catheters placed in a living mammal to perform a medical operation. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and Nicholas et al. before him or her to modify the fluid flow of Knoll to be influenced by the mechanical oscillation means connected downwards to peristaltic pumping means of Nicholas et al.; this is simply applying a known technique of applying mechanical oscillation means connected downwards to a peristaltic pump to a known device ready for improvement, being an apparatus for performing pressure measurements, to yield the predictable result of the electroconductive liquid oscillating in movement when entering the lumen of the catheter. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a "method for inducing an oscillating flow of ... fluid" (col. 1 lines 16-17) as taught by Nicholas et al. Therefore, it would have been obvious to combine Knoll with Nicholas et al. to obtain the invention in the instant claim 13.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knoll (US 6450972 B1) as applied in claim 1 above, and further in view of Ogawa et al. (US 5846210 A).

Knoll does not appear to explicitly disclose a method wherein the alternative current frequency applied to the liquid substance is comprised between about 60 and 130 kHz, preferably between about 80 and 120 kHz. However, Ogawa et al. teaches disclose a method wherein the alternative current frequency applied to the liquid substance is comprised between about 60 and 130 kHz, preferably between about 80 and 120 kHz ("high-frequency current is preferably such that the frequency and power are about 100" col. 8 lines 16-17).

Knoll and Ogawa et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly medical instruments placed in a living mammal to perform a medical operation. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and Ogawa et al. before him or her to modify the alternative current frequency applied to the liquid substance of Knoll to include the comprised current frequency to be between 60 and 130 kHz of Ogawa et al.; this is simply combining prior art elements of currents with specific ranges of the current frequencies to obtain predictable results of a current frequency in a desired range. It is known to one of ordinary skill in the art that alternative current frequencies can be applied to liquids in a multitude of ranges. Ogawa et al. teaches that current frequencies have already been applied in medical instruments. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a provide a "high-frequency current through [a] guide wire"

(Abstract lines 3-4) as taught by Ogawa et al. Therefore, it would have been obvious to combine Knoll with Nicholas et al. to obtain the invention in the instant claim 8.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean P. Dougherty whose telephone number is (571) 270-5044. The examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. P. D./

/Joseph S. Del Sole/
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